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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,158	09/29/2006	Hans Jorg Meisel	17346-0033	2935

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EXAMINER

SCHNEIDER, LYNN SY M

ART UNIT	PAPER NUMBER
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3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,158	Applicant(s) MEISEL, HANS JORG	
	Examiner LYNNSY SCHNEIDER	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 5-7, 9-16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishijima et al. (Pat. No. US 5,899,941) in view of William et al. (Pub. No. US 2004/0010316 A1).

Regarding claims 1-3, 5-7, 9, and 10, Nishijima et al. discloses a parts assembly 2, 3 (figure 1A) for a prosthesis 1, particularly a cervical spine intervertebral disc prosthesis, comprising two base parts 2, 3, which are coupled to one another in an articulated manner by means of coupling parts 11, 15 (figure 1B) formed on the base parts 2, 3, wherein the base parts 2, 3 are in each case formed in one piece with an associated coupling part 11, 15, wherein the base parts 2, 3 and their associated coupling parts 11, 15 are made of the same material (col. 5, lines 20-30). An anatomically adapted contact surface 6, 7 (figure 3A) is formed on a respective outer side of the two base parts 2, 3 (figure 3A). An anti-rotation means 20, 20a (figures 1A, 2) is formed on each of the two base parts 2, 3. The anti-rotation means 20, 20a comprises a web arranged on the respective outer side (col. 3, lines 30-33). The two base parts 2, 3 are coupled to one another in an articulated manner by means of a sliding connection (figures 4-6B). The sliding connection is embodied by means of a

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sliding surface “arc shape” formed on one of the coupling parts 11 and a countersliding surface 15, which is adapted to the sliding surface “arc shape” and is formed on another of the coupling parts 3, wherein the sliding surface is slidably supported on the countersliding surface in the coupled state of the two base parts 2, 3 (figure 1A). The sliding surface is formed on a hemispherical protrusion 11 on the coupling part 11 (figure 1A; col. 2, lines 64-67). The two base parts are at least partially coated (in the region of the webs, there is a hydroxyapatite coating). The webs have a material coating (col. 5, lines 33-36).

Regarding claims 11-16, 18, and 19, Nishijima et al. discloses a part for a prosthesis parts assembly (figure 1A), particularly a cervical spine intervertebral disc prosthesis part, comprising a base part 2 and a coupling part 11 formed on the base part 2 for articulated coupling to another base part 3 (figure 1A), wherein the base part 2 and the coupling part 11 are formed in one piece, and made of the same material (col. 5, lines 20-30). An anatomically adapted contact surface 6 on an outer side of the base part 2 is provided (figure 3A). An anti-rotation means 20, 20a on the outer side of the base part 2 is provided (figures 1A, 2). The anti-rotation means 20, 20a comprises a web arranged on the respective outer side (col. 3, lines 30-33). A curved sliding surface “arc shape” is formed on the coupling part 11. The two base parts are at least partially coated (in the region of the webs, there is a hydroxyapatite coating). The webs have a material coating (col. 5, lines 33-36).

Nishijima et al. does not disclose wherein the material is a material selected from the following group of materials: polyetherketone (PEK), polyetheretherketone (PEEK),

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polyacryletherketone (PAEK), polyetherketoneketone (PEKK),
polyetherketoneetherketoneketone (PEKEKK) and
polyetherketoneetherketone (PEKEK).

However, William et al. teaches that first and second implant members 12, 14 can be manufactured from a plurality of biologically compatible materials, including PEEK and PEKEKK (paragraph 0065).

It would have been obvious to one skilled in the art at the time the invention was made to manufacture the base parts and coupling parts from PEEK or PEKEKK, as taught by William et al. since William et al. discloses that such materials are two of the many biocompatible options commonly known to one skilled in the art for manufacturing spinal implants. Furthermore, it is well known that PEEK and PEKEKK have desirable wear characteristics.

3. Claims 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishijima et al. in view of William et al. and further in view of Ogle et al. (Pat. No. US 6,322,588 B1).

Regarding claims 8 and 17, Nishijima et al. as modified by William et al. discloses all of the claimed elements, except for the sliding surface and the countersliding surface being coated with a coating material based on a chromium-nickel alloy.

However, Ogle et al. teaches coating medical implants, and particularly spinal implants (col. 3, lines 44-45) with a cobalt-nickel-chromium alloy (col. 4, lines 13-23) for the purpose of improving the mechanical properties of the implants (col. 2, lines 25-34).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to coat the spinal implant of the Nishijima et al. reference as modified by Williams et al. with a cobalt-nickel-chromium alloy as taught by Ogle et al. for the purpose of improving the mechanical properties of the spinal implant.

Response to Arguments

4. Applicant's arguments filed 5/24/2010 have been fully considered but they are not persuasive.

5. In response to Applicant's argument that Nishijima does not teach or suggest forming the one piece parts 2, 3 from a single material, it is noted that col. 5, lines 20-35 discloses that "the first and second bodies 2, 3 are formed of ***a material*** having stability inside the living body...for example, ***the material*** of the first and second bodies comprises stainless steel, titanium, etc...". As shown in the figures, by the uniform cross-hatching, each piece 2, 3 is uniform and created as a single piece.

6. In response to Applicant's argument that Williams does not teach forming the concave bodies 18 and 22 of the claimed materials, Examiner would like to point out that paragraph 0065 teaches forming implant parts 12 and 14 from PEEK or PEKEKK, and paragraph 0059 discloses that implant part 12 is comprised of an anchor plate 16 and a concave body 18; and implant part 14 is comprised of anchor plate 20 and a convex body 22. Therefore, Williams is not silent regarding the material of the coupling parts, since paragraph 0065 specifically teaches forming a first implant part and a second implant part, each comprising a base part and a coupling part, from PEEK or PEKEKK. Furthermore, it is noted that Williams does not need to teach forming the

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coupling parts specifically of PEEK or PEKEKK, since the mere teaching of forming an implant of the specified materials is sufficient to overcome the deficiency of Nishijima (i.e., a teaching in the prior art of forming an implant of PEEK or PEKEKK would be sufficient to modify the two unitary pieces 2, 3 of Nishijima to be made of PEEK or PEKEKK).

7. Since Nishijima discloses base parts and coupling parts formed as a single, uniform piece, and discloses that each single uniform piece can be formed of a biocompatible material, and William teaches forming every piece of an implant from a biocompatible material such as PEEK or PEKEKK, the rejection in the non-final office action dated 2/25/2010 is proper.

8. Regarding the rejection over Nishijima in view of William and further in view of Olge, since Applicant has not presented arguments regarding the specific combination of references in the rejection, the arguments are moot.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNNSY SCHNEIDER whose telephone number is (571)270-7856. The examiner can normally be reached on Monday - Friday, 9:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. S./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733